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ORIGINAL ARTICLE

The Lombardia Stroke Unit Registry: 1-year experience of a web-based hospital stroke registry

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Abstract This paper presents methodological aspects of the Lombardia Stroke Registry. At the registry start-up, 36 recruiting centres were identified according to a regional survey. The registry recruits consecutive patients with acute stroke or transient ischaemic attacks (TIAs). A 3-month follow-up was planned to correlate acute care with outcomes. On 31st December 2007, data concerning 6,181 patients discharged alive were available. The registry aims at measuring performance parameters, identifying guidelines non-compliance and analysing care processes. In this first phase, 30% of the Lombardia acute stroke and 10% of TIA patients have been enrolled, thus the sample can be considered informative for the disease care in the region. The proportion of completed data items is very high with very small differences among items. The following critical points were highlighted: (1) lack of data input staff for 30% of centres, and (2) difficulty of obtaining the informed consent for post-discharge follow-up.

Keywords Cerebrovascular diseases · Stroke unit · Process of care · Registry

On behalf of SUN Lombardia Collaborators.

A list of participants of SUN Lombardia Collaborators is given in "Appendix".

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Background

Stroke is the third leading cause of death and long-term disability in most industrialised countries and it accounts for a considerable proportion of healthcare spending [1]. The results of controlled randomised clinical trials and meta-analysis reviews show that access to specialised stroke units benefits stroke patients in terms of mortality (3% absolute risk reduction), institutionalisation and dependency (overall 5% absolute risk reduction) [2–4]. However, many issues relating to stroke diagnosis and therapy and to the organisation of stroke care remain to be resolved and little is known about how these units can be rendered more effective [5].

To address these questions, many hospital and population-based stroke registries have been set up over the past decade, with the aim of identifying specific key indicators able to monitor/measure systematically the quality and adequacy of acute stroke care [6]. Disease registries seem to be appropriate tools for collecting the data needed to analyse care processes [7–11], data which are useful both in national healthcare planning and in scientific research.

In spite of this strong scientific evidence, Italy still has few hospitals equipped with the specialised facilities and personnel necessary to accommodate and treat stroke patients according to the latest guideline recommendations [12], and to date no Italian Stroke Registry Study has focused specifically on care processes [13–16].

The Lombardia regional healthcare programme for the period 2000–2004 included plans to implement new semi-intensive stroke units, named "Unità di Cura Cerebrovascolari (UCV)", the aim being to accommodate and treat at least 70% of all hospitalised stroke patients in these units. This period also coincided with the development, by the regional sections of two Italian neurological societies—SIN (Società Italiana di Neurologia) and SNO (Società Neuroscienze Ospedaliere)—of a Stroke Unit Network (SUN), created as a means of coordinating and streamlining the care process in these units and of optimising resources and outcome. The SUN Lombardia, which brings together 36 stroke units (see the complete list in "Appendix"), aims to improve the quality of stroke care both in the acute and the post-acute phase, and to encourage the creation of efficient links among hospitals involved in stroke care, in order to ensure prompt definition of patients' needs and to promote swapping of opinion and experiences on clinical and therapeutic topics [17]. Recognising the usefulness of the disease registry as a resource, the SUN made the creation of a web-based stroke registry as one of its first priorities.

The Lombardia Stroke Unit Registry was established in 2006 with the aim of improving stroke care in Lombardia through verification of the quality (efficacy and efficiency) of the participating stroke units, and the generation of important, constantly updated data, making it possible to monitor progress in reducing the incidence of stroke and associated disability and mortality. A particular aim was to identify specific parameters that can be used as quality indicators/markers of the care process. In this regard, the comparison of different registry data (current and past) was expected to highlight what changes (if any) to the care process might be appropriate in order to reduce morbidity and mortality after a stroke has occurred.

In this paper, methodological aspects of the project are presented and the data for the first 12 months of the Lombardia Stroke Unit Registry are used to discuss the implementation of the registry.

Methods

Selection of the recruiting centres

The main purpose of the Lombardia Stroke Unit Registry is to assess the diagnostic–therapeutic process followed in patients admitted to Lombardia-based stroke units or hospital departments serving as stroke units.

In this study, the following definition of stroke unit was adopted: "acute ward area with stroke-dedicated beds (at least 80% of admitted patients suffering from stroke) and a dedicated team (at least one full-time physician and nurse caring exclusively for acute stroke patients)" [18].

To identify possible recruiting centres, we used data from a regional audit of the general directors of all the hospitals in Lombardia that had discharged at least 50 acute stroke patients in the course of 2005. Thirty-six centres were identified. A formal invitation to participate in the registry project was sent to the medical director of each centre. On receiving their acceptance, a structured questionnaire was mailed to the project coordinator at each centre, so that the characteristics of each individual stroke service could be assessed. The questionnaire items were based on care quality indicators drawn from the PROSIT survey questionnaire [18]. Briefly, the questionnaire included quality indicators relating to the hospital setting (the presence of an emergency room, intensive care facilities, neurosurgery, vascular surgery, rehabilitation and neuroradiology departments), the stroke unit itself (number of beds and percentage of monitored beds, presence of stroke outpatient service), the staffing of the unit, the care process (adoption of written protocols and of the SPREAD Italian stroke guidelines [19], number of multidisciplinary meetings), and the diagnostic services (24/7 availability of brain CT, brain MRI, echocardiography, ultrasound and cerebral angiography, and Holter ECG).

Thirty-five centres out of the 36 contacted agreed to participate and completed the questionnaire. One centre failed to complete and return the questionnaire, without providing any justification.

The Lombardia Stroke Unit Registry

The Lombardia Stroke Unit Registry, a hospital-based stroke registry, was developed by the scientific committee of the Lombardia section of the SUN (founded in 2002 by the regional sections of SIN and SNO), also taking into account previous international experiences. The stroke care performance indicators selected were based on the SPREAD [19] guideline standards for in-hospital acute stroke care and covered actions taken between emergency department admission and hospital discharge. A 3-month follow-up visit was scheduled in order to correlate acute stroke care performances with the patient's health outcome, measured in terms of survival and disability.

The method of selecting data elements for inclusion in the registry was similar to that used in the development of the Paul Coverdell National Acute Stroke Registry [20]. In particular, the SUN scientific committee, reviewing the SPREAD guidelines which highlight the most relevant measures and clinical findings, produced a preliminary list of items. In March 2006, the scientific committee organised a meeting with the centre coordinators to review and update the preliminary list, assess performance measures,

and reach consensus on steps needed to improve the quality of stroke treatment. The participants reviewed and discussed established stroke registry parameters before making their recommendations. Agreement, shown either verbally or by raising a hand, had to be reached among all participants before an element was added to the list. Other aspects considered and discussed before adding a data element to the registry were: the validity of the evidence, i.e. the existence, or otherwise, of sufficient scientific evidence to support a positive link between a performance measure and outcome, and measurement feasibility, i.e. the information needed in the medical record to assess adherence.

At the end of the meeting, the scientific committee produced a user's guide including standardised definitions of all data elements and methods for data collection. This guide was sent to the participating centre coordinators and abstractors.

The registry was designed to collect consecutive patients with acute ischaemic stroke, transient ischaemic attack (TIA), intracerebral haemorrhage and subarachnoid haemorrhage.

Data were collected retrospectively, from clinical records, selecting patients on the basis of their hospital discharge codes. For this purpose, the following ICD-9-CM (International Classification of Disease, ninth revision, clinical modification) codes were used: 430, 431, 433.01, 433.11, 433.21, 433.31, 433.81, 433.91, 434.01, 434.11, 434.91, 435, 436. Stroke neurologists confirmed case eligibility. Trained abstractors entered prescribed data elements abstracted from local medical records into a software application provided, for the Lombardia Stroke Unit Registry, by TSD Projects (http://www.tsd-projects.it). This application uses real-time error checking and data verification tools. In particular, it controls data ranges, forces double entry of key data, and checks consistency of dates. Data are collected, transmitted and stored in accordance with current privacy and personal data protection laws, and aggregated in an anonymous database for statistical purposes. The database was managed at the coordinating centre, which was responsible for the overall data quality checking. Reports of missing data and errors were generated for each hospital by the coordinating secretary.

Implementation of the registry began in May 2006 and by July 2006 all the centres were operational and the web-network had been verified. In the same month, the abstractors had a 1-day training session on the techniques of chart abstraction, standardised data definition and the use of the data abstraction tools. After a general presentation, the participants practised chart abstraction from three sample records. The abstractors were all neurologists, neurology students or nurses with expertise in stroke and data collection. From August to December 2006, each trained abstractor had to gather data elements from the medical records of 20 patients and enter them into the database. Data quality was monitored by frequently running queries to detect inconsistent responses, and by means of random re-abstractions done by the SUN data monitor. Discrepancies between data abstracted by the SUN monitor and by the hospital abstractors were discussed with the abstractors and additional training was provided as necessary.

On 1st January 2007 the Lombardia Stroke Unit Registry began recruiting patients. Provision was made for a first-phase 12-month recruitment period (January to December 2007) and for a follow-up of each patient 3–4 months after discharge. The follow-up period (during which patients were seen as outpatients or interviewed over the telephone by the reference physician) ended in April 2008.

Ethics

All the participating stroke centres submitted this study to their local ethics committees. The need for informed consent from patients or their surrogates, both for inclusion in the study and for the 3-month follow-up visit/interview was discussed in the light of the results of phases 1 and 2 of the Canadian Stroke Network registry project. The Canadian Stroke Network data demonstrated that, despite the best efforts of these researchers, only just under half of the eligible patients consented to participate, and that there were significant differences between those who did and those who did not agree to take part [21].

The ethics review boards in the hospitals participating in the present study approved the collection of in-hospital data even without explicit consent. Instead, consent was mandatory for the 3-month follow-up evaluation.

Computer-based tools

The registry was supplemented by the addition of some ancillary tools, serving mainly for monitoring patient enrolment, verifying the compliance of the recorded medical actions with the SPREAD guidelines, and analysing the care process in the different centres. All these applications were developed to run on top of the relational database of the registry.

Enrolment monitoring

The enrolment monitoring tool can be used to generate statistics on the activity of the various centres. On the basis of existing statistics and epidemiological data, it is possible to work out, for each centre, a target number of patients to be enrolled in a given period of time. Comparing the

number of patients expected to be recruited with the number actually recruited is, for the registry coordinator, a useful means of detecting under-performance early on, allowing, when possible, opportune corrective measures to be taken. This enrolment monitoring could create a kind of *fruitful competition* among centres, especially if they are periodically sent their own curves together with those of the best-performing centres.

Guideline compliance verification

In a previous study [22], we demonstrated an association between stroke outcome and compliance with the SPREAD guidelines, albeit in a small patient sample. Similar results are described in [23], in this case based on a specific computerised clinical chart adopted in the stroke unit at the C. Mondino Institute of Neurology, Pavia, Italy. Data from the Lombardia Stroke Unit Registry can be used to confirm these findings on a larger and more geographically widespread sample. Moreover, this process may allow major areas of non-compliance to be highlighted, and compared among the different clinical centres. To these ends, the RoMA (Reasoning on Medical Actions) tool was developed [24, 25]. This tool automatically matches stored patient information with guideline rules and thus makes it possible to detect non-compliances. Being a general framework, RoMA can work with any guideline rules and may be linked to any database, subject to transfer of the data to its middle layer. Its functionality is thus guaranteed for any future release of the registry. The storage of the guideline rules in a computer-based relational table format is facilitated by the fact that, with the exception of a few free-text items, all the data in the registry are encoded.

Due to the synthetic character of the registry, not all the SPREAD recommendations can be checked: on analysing the registry data model, we ascertained that compliance could be tested for 28 recommendations, 20 referring to the acute phase and 8 to the secondary prevention phase.

The Rankin Scale score provides a pre-stroke value, a value at discharge and a value at follow up: these values, together with mortality and stroke recurrence information data are the outcome variables to be related to compliance. Given the complexity of the statistical analysis process needed to arrive at this kind of inference, data export functionality is used to prepare a set of anonymised data that can be imported into a statistical package.

Process mining

Recent literature on cerebrovascular diseases provides evidence that a "process-based" approach can improve the efficiency of a healthcare organisation: in a 3-year study by Vos et al. [26], improving process coordination in a Maastricht hospital was found to reduce the average stroke unit stay from 12 to 7 days; Kwan and Sandercock [27], on the other hand, illustrate the use of "care pathways" as a means of implementing evidence-based medicine in stroke care. The Lombardia Stroke Unit Registry, being a source of a significant amount of data, may be seen as an important opportunity not only to perform reliable statistics, but also to derive information about the stroke care process. Both can be done through the opportune use of *information and communication technologies*. The registry also stores temporal information relating to most of the performed medical actions. Symptom onset, arrival at the emergency department, neurological evaluation and neuroimaging are all time-stamped, while for many other procedures, semi-quantitative time-intervals are reported (e.g. within 3 h, within 24 h, etc.). In this way it is possible to track a significant portion of the care process. The technique used to achieve this is called "process mining", a term describing a family of algorithms that are able to extract process information from raw temporal data [28], called "event logs". These algorithms are actually implemented and available in software packages like ProM [29], which we use to analyse SUN logs.

While the main purpose of process mining is to highlight the presence of process models, additional analyses on organisational aspects and performance can also be performed. For example, if we had information about *who* carried out the different procedures, it should be possible to perform a "social network analysis", i.e., to reconstruct the network of healthcare professionals collaborating in a given care process. For healthcare organisations, analyses of this kind are a means of monitoring the intensity, and also the results, of such collaborations. Moreover, in this way, it is also possible to highlight bottlenecks and calculate efficiency indicators, such as the execution times of certain actions/processes and the interval of time elapsing between two particular actions. Greater insight into this issue is offered in [30], where examples of process comparison between different centres are provided.

Results

Hospital characteristics and patient enrolment

The data elements included the service assessment structured questionnaire are listed in Table 1. Thirty-five centres completed and returned the questionnaire. In April 2006, 28 units (80%) fulfilled the definition of a stroke unit, and the other seven were neurology departments. Monitored beds were available in 30 centres, 28 stroke units and two neurology departments. Ten of these 30 centres (all stroke units) had only monitored beds. In the other 18 stroke units,

Table 1 Hospital-level data elements

Data elements	Code
Hospital setting	
Academic	Yes/no
Staffed beds	Number
Emergency department	Yes/no
Neurosurgery department	Yes/no
Resuscitation ward	Yes/no
Vascular surgery department	Yes/no
Intensive cardiac unit	Yes/no
Neuroradiology department	Yes/no
Interventional radiology	Yes/no
Rehabilitation department	Yes/no
Stroke unit	Yes/no
Stroke team	Yes/no
Unit setting	
Acute stroke care beds	Number
Acute stroke care monitored beds	Number
Monitoring capability	
Cardiac rhythm	Yes/no
Blood pressure	Yes/no
O_2 saturation	Yes/no
Neurological evaluation (NIHSS)	Yes/no
Availability of diagnostic facilities	
CT	24 h/7 days, 12 h/7 days, 12 h/5 days, no
MRI	24 h/7 days, 12 h/7 days, 12 h/5 days, no
Angiography	24 h/7 days, 12 h/7 days, 12 h/5 days, no
Carotid duplex scanning	24 h/7 days, 12 h/7 days, 12 h/5 days, no
Transcranial Doppler	24 h/7 days, 12 h/7 days, 12 h/5 days, no
Holter ECG monitoring	24 h/7 days, 12 h/7 days, 12 h/5 days, no
Echocardiography (transthoracic/transoesophageal)	24 h/7 days, 12 h/7 days, 12 h/5 days, no
Staffing	
Physicians trained in stroke care	Number of full-time physicians
Nurses trained in stroke care	Number of full-time nurses
Therapists	Number of full-time therapists
Process of care	
Knowledge and implementation of SPREAD guidelines	Yes/no
Written stroke protocols	Yes/no
Thrombolytic therapy	Yes/no
Multidisciplinary meetings	Yes/no, number
Dedicated outpatient visits	Yes/no

33% of the beds, on average, were monitored beds (range 9–60%), a slightly lower proportion than the 50% envisaged by the Directorate-General for Health of the Lombardia Region in its decree n. 10068, 18 September 2008 (act no. 864). Table 2 reports the re-classification, in the light of the recent regional guidelines, of the centres participating in the registry.

Ten of the 35 centres were academic hospitals. The mean number of staffed beds per hospital was 614 (range 50–1,521). All the units except one ($n = 34$, 97%) were in hospitals equipped with an emergency room; 34 hospitals (94%) had an intensive cardiac unit, 33 (91%) had resuscitation and rehabilitation wards, 26 (72%) had a vascular surgery department, and 13 (36%) a neurosurgery department. All the hospitals had 24-h CT and/or MRI facilities and 50% had an angiography room. Carotid ultrasound and transcranial Doppler examinations were available in all the centres, and 19 units (53%) could carry them out 24 h a

Table 2 UCV level of the stroke units participating in the registry

Criteria	UCV level	No. of stroke unit
Multidisciplinary team	1, 2, 3	28
Diagnostic equipment (carotid sonography, transcranial Doppler, echocardiography)*	1, 2, 3	28
Dedicated stroke staff	1, 2, 3	28
Early rehabilitation	1, 2, 3	28
CT scan 24 h/7 days a week	1, 2, 3	28
Thrombolitic therapy for stroke	2, 3	25
Neurosurgeon available on demand	2, 3	25
Neuroradiology	3	10
Interventional radiology	3	5
Neurosurgery ward	3	13
Vascular surgery ward	3	26
Intra-arterial thrombolisis	3	5
UCV 1st level		3
UCV 2nd level		20
UCV 3rd level		5

* At least one

day/7 days a week. Twenty-four units (67%) could carry out echocardiography. The SPREAD stroke guidelines were known and followed in 34 centres, the other centre declaring that it was aware of them but was unable to adopt them due to organisational difficulties; written care protocols were available on-site in 33 centres and diagnostic-therapeutic protocols in 28; at least one multidisciplinary meeting was held every fortnight in 28 centres. Thirty (83%) centres followed up stroke patients after discharge through specific outpatient visits.

In 2006, the centres discharged a total of 11,350 DRG14 patients (62% of the regional DRG14 total) and 3,905 from DRG15 (52% of the regional total for this group). Five centres never began the recruitment phase due to lack of staffing for data input and six centres recruited fewer than 50 patients with acute stroke. The data of these six centres were excluded from the registry on account of the high risk of recruitment bias and of low data quality. Twenty-four centres carried out the recruitment phase.

On 31st December 2007, data for 6,181 patients were available; of these, 5,203 were stroke unit patients (3,752 from comprehensive stroke units) and 978 were patients treated in neurology departments. The mean number of patients per centre was 257 (range 93–870). The stroke diagnosis at discharge was haemorrhagic stroke in 815 (13%) patients, ischaemic stroke in 4,629 (75%) patients, and TIA in 737 (12%) patients. These data represent 30% of the acute stroke patients and 10% of the TIA patients admitted to Lombardia hospitals in the period in question.

Four hundred and eighty-six patients (8%) died during the hospitalisation and 647 (10%) did not give their informed consent to the follow-up visit. Follow-up visit data were available for 4,848 patients (96%) of the 5,048 patients who were discharged alive, giving their informed consent to the follow up.

Data elements

The data elements identified by the centre coordinators for inclusion in the registry covered patient-level data, divided into demographic data plus four domains that reflect the entire timeframe of acute stroke care from onset of symptoms through treatment to follow up, namely: (1) emergency evaluation and treatment data, (2) in-hospital evaluation and treatment data, (3) discharge data, and (4) post-discharge follow-up data (Table 3).

The demographic data section included items, such as age, gender and race, that may be related to treatment delay and outcome. The data elements referring to events in the emergency room, intended to identify key processes that might delay the initiation of thrombolytic therapy, included the date and time of the patient's arrival in the emergency department, the date and time of the onset of symptoms, the date and time of the neurological evaluation, information on the diagnostic work-up (in particular, the type, date and time of initial brain imaging, National Institute of Health Stroke Scale score, pre-stroke Rankin Scale score), treatment administered (systemic/intrarterial thrombolysis, aspirin, etc.), and inclusion in clinical trials. The in-hospital evaluation and treatment data elements were designed to allow monitoring of the quality of care during the period of hospitalisation for stroke and evaluation of the homogeneity of stroke care across Lombardia hospitals. They included current stroke risk factors (coded as present or

Table 3 Structure of registry data collection process

Phases	Variables
Demographic data	Birth date, gender, race, tax code, telephone number
Emergency evaluation and treatment	Arrival date and time; date and time of onset of symptoms; date and time of neurological evaluation; type, date and time of neuroimaging; pre-stroke modified Rankin Scale score; NIHSS score; acute phase treatments
In-hospital evaluation and treatment	Date of hospitalisation; risk factors; diagnostic examinations (types and times); care procedures (types and times); complications; treatments; surgical and/or endovascular procedures; rehabilitation
Discharge	Date and type of discharge; NIHSS score; modified Rankin Scale score; Barthel Index score; diagnosis; TOAST classification; ICD-9CM code diagnosis; treatments; educational recommendations
Post-discharge follow up	Date of follow up; clinical conditions (alive or dead); cause of death; NIHSS score; modified Rankin Scale score; adverse events (complications or new events); subjective evaluation of functional recovery

absent), diagnostic and surgical procedures (type and timing, coded as $\leq$6 h, $\leq$12 h, $\leq$24 h, $\leq$48 h, $\leq$72 h, $\leq$7 days and >7 days from admission), time of initiation of any antithrombotic therapy, care procedures [DVT prophylaxis within 48 h of arrival, screening for dysphagia, bedside swallow screen, continuous monitoring of vital parameters (ECG rhythm, blood pressure, O_2 saturation), nasogastric feeding, bladder catheter placement and early mobilisation], occurrence of medical/neurological adverse events (coded as present or absent), and time of initiation of a rehabilitation treatment (coded as $\leq$6 h, $\leq$12 h, $\leq$24 h, $\leq$48 h, $\leq$72 h, $\leq$7 days and >7 days from admission). Risk factors, associated conditions and adverse events were defined in accordance with the SPREAD guidelines.

The discharge data elements included date of hospital discharge, discharge status (alive or dead), NIHSS score, Rankin Scale score, Barthel Index score, discharge plan (setting, treatment, education), ICD-9-CM code for principal and secondary diagnosis, and aetiopathogenetic classification of ischaemic stroke subtype (TOAST classification).

Post-discharge follow-up data elements included details of patient's function, treatment and intercurrent diseases, collected at an assessment 90 days after discharge.

Completeness and quality of data

Throughout the study period, monthly data checks were performed by the coordinating centre and a report was generated for each participating centre. At the end of the first year the completeness of the registry was evaluated and critical points were discussed in an effort to find solutions for the second phase of the registry project. An audit procedure on 10% of cases per centre is under way and the results of this will be published in the next few months. We decided to wait until the end of the first year before activating this audit procedure as it has been argued that the benefits observed in some studies can be attributed to temporary modifications of practice patterns or improvements to documentation and abstraction procedures induced by the implementation of the chart audit, rather than to a real change in practice patterns prompted by feedback. Aware, too, that giving feedback from chart audits can constitute, in itself, a quality-improvement strategy, we wanted to rule out any risk of influencing practice patterns, because the main objective of the first year of the project was simply to describe the ongoing process of care. Thus, at the end of the data collection, we began the audit procedure which, on the other hand, is essential in order to guarantee the quality of the registry.

Analysis of the completeness of the data showed that it ranged from 93 to 100%. The lowest rates of completeness were those recorded for the following items: birth date (99.6%) in the demographic section, neuroradiological imaging (93%) in the emergency evaluation and treatment section, and anti-platelet treatment (98.6%), anti-coagulant treatment (97.4%) and rehabilitation (98.4%) in the in-hospital evaluation and treatment section. Total completeness of data (100%) was recorded for all the elements considered in the discharge and follow-up sections.

Conclusions

The main objective of the Lombardia Stroke Unit Registry project is to collect data relating to clinically important quality measures and to improve the delivery of evidence-based stroke care. Unlike other stroke registries, such as the one set up in Malmö [31], that focus on the epidemiology of stroke, our registry, like the more recent programmes of this kind [19–21, 32], aims to support quality improvement in the delivery of care. In the US, the results from four pilot prototypes of the Paul Coverdell National Acute Stroke Registry [33] showed, in relation to measures of less complex interventions, including dysphagia screening, lipid profile measurement and smoking cessation counselling, that there is considerable room for improvement in these areas, given that only between a third and half of eligible patients were found to receive these interventions.

The "Get with the Guidelines" programme, which used an Internet-based data collection and decision support system, demonstrated a significant improvement in 11 out of 13 quality measures for stroke [34]. In the US, stroke registries have been promoted as a means of increasing the use of currently underused interventions (prophylaxis of DVT, initiation of antithrombotic medication within 48 h and at discharge). Voluntary participation in a web-based acute stroke treatment registry was associated with a significant improvement in the use of such interventions [35].

We developed our registry in the light of these previous, international experiences and its development ran parallel with initiatives, conducted in pursuit of the same objective (i.e. to improve the quality of stroke care), mounted by the Lombardia Regional Health agency. The data elements included allow the measurement of parameters that reflect adherence to SPREAD guideline recommendations. Furthermore, implementation of the RoMA software allows real-time detection of non-compliance with guidelines and the process mining analyses the identification and comparison of different processes of care. These particular aspects of our registry—measures of performance parameters, identification of non-compliance and analysis of the process of care—can help to pinpoint areas where care can be improved, as well as contribute to efforts to establish the best diagnostic and therapeutic patterns for the different types of acute stroke unit and help to educate stroke physicians and raise awareness among them of the importance of adherence to guideline recommendations.

In this first phase of the registry we collected the data of 30% of Lombardia acute stroke patients and of 10% of Lombardia TIA patients. These percentages are similar to those observed in the first phase of other registries [32] and can be considered to reflect current acute stroke care in Lombardia. We recorded very high rates of completeness of data, with only very small differences emerging between items. In accordance with previously reported findings [36–38], the use in our registry of clear definitions of data elements and the availability of guidelines for their collection contributed to their completeness. The high level of communication between investigators and the coordinating centre during the data collection and processing stages may also have positively influenced the quality of the data. For the second phase of the registry project we will optimise the online data dictionaries and the data checks, also on the basis of the results of the audit we are currently performing.

One critical problem emerged from this first analysis: five units never started data collection and a further six showed very low enrolment rates. In other words, 30% of the centres could not be included in the registry. The main reason for this was the lack of staffing for data input. The costs associated with data collection and quality improvement are difficult to quantify and, as a result, the initial phases of registry implementation are often poorly financed. However, in view of the huge burden that stroke places on the economies of industrialised countries, this is probably a false economy; indeed, improved stroke prevention and care could offer significant money-saving opportunities [39]. To design a sustainable regional registry for stroke quality improvement, there is a need for collaboration among key partners in the areas of medical research and medical policy-making, including healthcare providers, healthcare systems and regional health agencies. The provision of adequate funding for data collection and quality improvement activities is critical. In the second phase of the Lombardia stroke registry project, we anticipate closer collaboration with the regional health agency in order to obtain more funding and greater involvement of regional hospitals. Stroke performance measurement collection will no longer be voluntary but incentive-based with a view, ultimately, to the public reporting of verifiable data.

Another important issue was the need to obtain informed consent for the collection of post-discharge follow-up data. The measurable patient-care objectives that are linked to specific interventions must be seen as a tool for improving not only the process of care but also the patient's health outcomes. It is thus necessary to remove the barriers preventing access to critical information on patients after their discharge from hospital. The national and regional health agencies could provide considerable assistance towards reaching this important goal.

In the next few months we will submit for publication the results of our investigation of acute stroke care in Lombardia and of the impact of the various quality indicators identified on patient outcomes. Phase two of the Lombardia stroke registry project is due to start in the first months of 2010.

Appendix: Lombardia SUN centres and collaborators

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